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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/521,907	03/09/2000	Stale Petter Lyngstadaas	49121	2801
21874	7590	06/21/2004	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205				SAUNDERS, DAVID A
		ART UNIT		PAPER NUMBER
		1644		

DATE MAILED: 06/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 521,907	Applicant(s) LYNGSTADAA et al
Examiner SAUNDERS	Group Art Unit 1684	
<i>—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—</i>		
Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.		
<p>- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</p> <p>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</p> <p>- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.</p> <p>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</p>		
Status		
<p><input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>4/1/04</u></p> <p><input type="checkbox"/> This action is FINAL.</p> <p><input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 1 1; 453 O.G. 213.</p>		
Disposition of Claims		
<p><input checked="" type="checkbox"/> Claim(s) <u>28-35, 41-55, 65</u> is/are pending in the application.</p> <p><input type="checkbox"/> Of the above claim(s) _____ is/are withdrawn from consideration.</p> <p><input type="checkbox"/> Claim(s) _____ is/are allowed.</p> <p><input checked="" type="checkbox"/> Claim(s) <u>28-35, 41-55, 65</u> is/are rejected.</p> <p><input type="checkbox"/> Claim(s) _____ is/are objected to.</p> <p><input type="checkbox"/> Claim(s) _____ are subject to restriction or election requirement.</p>		
Application Papers		
<p><input type="checkbox"/> See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.</p> <p><input type="checkbox"/> The proposed drawing correction, filed on _____ is <input type="checkbox"/> approved <input type="checkbox"/> disapproved.</p> <p><input type="checkbox"/> The drawing(s) filed on _____ is/are objected to by the Examiner.</p> <p><input type="checkbox"/> The specification is objected to by the Examiner.</p> <p><input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p>		
Priority under 35 U.S.C. § 119 (a)-(d)		
<p><input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).</p> <p><input type="checkbox"/> All <input type="checkbox"/> Some* <input type="checkbox"/> None of the CERTIFIED copies of the priority documents have been received.</p> <p><input type="checkbox"/> received in Application No. (Series Code/Serial Number) _____.</p> <p><input type="checkbox"/> received in this national stage application from the International Bureau (PCT Rule 17.2(a)).</p>		
<p>*Certified copies not received: _____</p>		
Attachment(s)		
<p><input type="checkbox"/> Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ <input type="checkbox"/> Interview Summary, PTO-413</p> <p><input type="checkbox"/> Notice of Reference(s) Cited, PTO-892 <input type="checkbox"/> Notice of Informal Patent Application, PTO-152</p> <p><input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review, PTO-948 <input type="checkbox"/> Other _____</p>		
Office Action Summary		

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/1/04 has been entered.

Claims 28-35, 41-55 and 65 are pending and under examination.

The amendment of 4/1/04 has overcome the following bases of rejection set forth in the action of 9/30/03.

- 1) The 112, second paragraph rejections of claims 29-31, 50, 54 and 60.
- 2) The 112, first paragraph rejections pertaining to claim 28 for reciting, "administering to said graft".

Claims 28-35, 41-55 and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 28, step a) "suitable tissue" is unclear because it is not stated what property of the tissue renders it "suitable". The only properties that the tissue that the examiner can glean from the specification is set forth at page 2, lines 13-18 –e.g. "non-mineralized soft tissue comprising a substantial proportion of epithelial cells" and "other tissue with high regenerative properties." Note, however, that words such as "substantial" and "high" are relative terms that have not been defined in the specification.

In claim 1, steps c) "on said pre-treated" lacks antecedent basis, since nothing in step b) recites "pre-treating."

Regarding claim 29, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

In claim 30, line 2 "the site" lacks antecedent basis.

In claim 51 "the aggregates" lack proper antecedent basis.

In claim 54, line 3 it is not clear if "a mammalian recipient bed or lesion" refers to the bed or lesion of step b) or to a different bed or lesion. If the former applicant may recite – the – in lieu of "a."

In claim 55, the "cosmetically acceptable excipient" lacks antecedent basis.

Claim 65 is unclear as to whether it is intended to delete step b) of claim 28 (i.e. reverse the order of applying the enamel substance and the graft to the bed/lesion) or to add an additional step of applying the enamel substance, after step c). If applicant intends the former or both interpretation (s) then claim 28 would be unclear in step c) by reciting "pre-treated", since nothing would have been done to "pre-treat" the graft bed, before applying the graft.

Claims 28-35, 41-55 and 65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

was filed, had possession of the claimed invention. Claim 28 continues to recite new matter. Also new claim 65 recites new matter.

In claim 28 part a) the Markush group members “cell culture” and “suitable tissue” lack descriptive support. Applicant’s response of 4/1/04 has urged that passages at specification pages 2-3 support. The examiner does not consider the instant generic recitations supported.

Page 3, lines 20-26 variously refers to “cultured epidermal cells”, including “fibroblasts” and “dermal tissue cells”, and to “cultured keratinocytes.” These recitations pertaining to a particular subgenus of cultured cells fail to support the genus of cultured cells.

The examiner cannot find the term “suitable tissue” anywhere at pages 2-3. If applicant considers recitations of “tissue” at page 2, lines 15 and 17, as supporting, then the term “suitable tissue” is overly broad because the only kinds of “suitable tissue” described therein are “non-mineralized soft tissues comprising a substantial proportion of epithelial cells” and “other tissue with high regenerative properties.” Note however, that the terms “substantial” and “high” are relative terms, rejectable under 112, second paragraph.

Claim 65 lacks disclosure support by reciting “after application of the graft as described in step c).” Applicant has urged that page 28, lines 6-10 support; however the examiner notes that this passage does not explicitly recite “after application of the graft.” Few details are given, and it would be natural to read this passage as teaching

that the enamel substance was applied to the bed before the graft was applied. See also 112, first paragraph, enablement rejection infra.

Applicant's arguments filed on 4/1/04 have been fully considered but they are not persuasive for reasons set forth above.

Claim 65 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's disclosure at page 21 has given inadequate direction as to how one is to manage to apply the enamel substance "as a thin layer between the graft and recipient bed" at a time point "after application of the graft".

As noted supra, in the 112 description rejection, the examiner is not even convinced that applicant described such a process. The examiner cannot imagine how one could create a thin layer of enamel substance between the recipient bed and already applied graft. The only mechanism that the examiner can imagine would be via capillary flow between the bed and graft tissues. How would this create a "thin film" over the whole area of the bed? Any points where bed and graft tissue already adhere would not be penetrated by capillary flow; thus no complete "film" could be formed. Also applicant admits that the enamel substance aggregates at body temperature and pH; thus, there would likely be aggregation of the enamel substance at the edge(s) of the bed – graft interface; such aggregation would block flow of liquid phase enamel

substance toward the interior of the bed – graft interface and thus prevent formation of a “thin film” through the interface.

Regarding prior art of record in paper 12 and 14, note the following:

Hammerstrom et al (EP 0,263,086 and EP 0,337,967) teach application of the enamel substance to the tooth to be grafted and not to a graft bed or lesion. Thus Hammerstrom et al thus do not teach the invention of instant claim 28.

Mellonig is considered to merely teach application of EMD to a site of reconstructive surgery, to which nothing is grafted (page 11, col. 3); in any case, the EMD is applied to “exposed root surface” (page 13, col. 1), which is not a non-mineralized tissue as required by claim 1 step b).

Claims are allowable over prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Saunders whose telephone number is (571) 272-0849. The examiner can normally be reached on Monday to Thursday from 8 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/LR
June 4, 2004

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PRIMARY EXAMINER
ART UNIT 182-1647